

**DOCKET NO.:** UNMC-0030 (63124US)  
**Application No.:** 09/647,911  
**Office Action Dated:** May 4, 2004

**PATENT  
REPLY FILED UNDER EXPEDITED  
PROCEDURE PURSUANT TO  
37 CFR § 1.116**

## **REMARKS**

The Official Action dated May 4, 2004 and the references cited therein have been carefully reviewed. In view of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

### **Status of the prosecution:**

Claims 1-7 and 10-15 are pending in this application. Claims 4-7 have been withdrawn from consideration. Claims 8 and 9 were canceled in Applicants' previous response. The May 4, 2004 Official Action is a final rejection.

Claims 1-3 and 10-14 remain rejected under 35 U.S.C. §102(b) as allegedly anticipated by Walker et al., J. Virol. Dec. 1995, pp. 8173-8177.

Claim 15 remains rejected under 35 U.S.C. §102(b) as allegedly anticipated by Baker et al., J. Gen. Virol. (1995) Vol. 76, No. 8, pp. 2081-2084.

### **Amendments presented in this paper:**

Claim 1 has been amended to specify that the recited virus genome is a coxsackievirus genome comprising a *pol* gene encoding an RNA-dependent RNA polymerase. Claims 2-4, 6 and 7 have been canceled as non-applicable or redundant in view of the amendments made to claim 1. Claim 5 has also been canceled, but its subject matter is replaced in amended form by claim 31.

By way of explanation, it is noted that the recitation of "coxsackievirus" that now appears in claim 1 was also found in claim 4, which had been withdrawn from consideration

as being drawn to a non-elected invention. Further, new claim 31 is drawn to the same subject matter as claim 5, which also had been withdrawn from consideration as drawn to a non-elected invention. However, Applicants respectfully assert that coxsackievirus and coxsackievirus B3 are part of the elected invention; hence the amendments and additions are proper. In Paper No. 5, Applicants elected Group I, claims 1-15, and further elected subgroups wherein the polymerase is an RNA polymerase and the virus is an enterovirus. Coxsackievirus (and the B3 subgroup) fall into both these categories, inasmuch as coxsackieviruses are enteroviruses and possess an RNA-dependent RNA polymerase. It must be concluded, therefore, that the claim amendments are proper.

Furthermore, for the reasons set forth below, Applicants assert that the claim amendments submitted herewith overcome each of the rejections issued in the May 4, 2004 Official Action, and that the claims as amended are in condition for allowance.

**Claims 1, 10-15 and 31 are novel over the cited references.**

In order to be properly raised in a rejection under 35 U.S.C. §102, a reference must disclose each and every limitation set forth in the rejected claims. The claims as presently amended call for a coxsackievirus genome that produces an attenuated virus, which comprises at least one *pol* gene modification that causes the polymerase to have increased fidelity as compared with a polymerase from a virus genome that does not comprise the *pol* gene modification, wherein the increased fidelity results in a decreased reversion rate from attenuated virus to non-attenuated virus.

Both Walker et al. and Baker et al. disclose polioviruses having mutations in the *pol* gene. However, neither reference discloses a coxsackievirus genome comprising such mutations. Thus, neither Walker et al. nor Baker et al. identically disclose the invention as presently claimed, which specifically calls for a coxsackievirus genome, and therefore cannot be said to anticipate the invention. Withdrawal of the rejections of claims 1, 10-15 and new claim 31 under 35 U.S.C. §102(b) is therefore requested.

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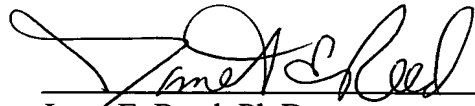
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**Conclusion.**

In view of the amendments submitted herewith and the foregoing remarks, the presently pending claims are believed to be in condition for allowance. Applicants respectfully request early and favorable reconsideration and withdrawal of the rejections set forth in the May 4, 2004 Official Action, and allowance of this application.

Respectfully submitted,

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